HYPPO HEADBOX

SERVICE MANUAL

XLTEK™

...making medical connections

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Introduction

Thank you for purchasing the Hyppo Headbox from XLTEK, one of the world's top manufacturers of neurodiagnostic and polysomnography equipment and software. XLTEK is an ISO 9001 certified company committed to providing you with technologically advanced products that are practical and easy to use.

XLTEK uses a vertically integrated process to design, build, test, distribute, and support its equipment. By retaining all of the processes within one organization, XLTEK maintains absolute control over the quality of its equipment. At the same time, XLTEK has the flexibility to improve products continually to meet your needs.

We encourage feedback and suggestions regarding any aspect of the Hyppo headbox, SleepWorks system (the MS-7 pulse oximeter), documentation, accessories, and support services.

With the new mechanical design and the latest software release, the Hyppo provides reliability and performance.

- Connects to XLTEK desktop computer.
- 26 referential AC inputs.
- 6 differential AC inputs.
- 4 non-isolated DC inputs for connection to XLTEK patient worn transducers.
- 4 isolated DC inputs for connection to external equipment.
- Built-in Masimo SET MS-7 pulse oximeter.

We strongly recommend that you read the “Warnings and Cautions” section of this manual before operating this headbox.

Intended Use

The Hyppo headbox is indicated for polysomnography (PSG) recording or for clinical EEG applications. It does not support pulse, beep or alarm sounds, or pulse waveforms. The Hyppo headbox is intended to be used along with SleepWorks software for diagnostic purposes, and should NOT be used as an apnea monitor.

The Masimo SpO2 Technology and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for adult, pediatric, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

Hyppo Part Number: 10230

Using This Manual

This service manual provides information and instructions that will help you set up and operate the Hyppo Headbox.

Detailed operation and customization of the SleepWorks system is described in the online documentation for NwDb and SleepWorks. When applicable, instructions are supplemented with warnings and notes:

Denotes a **warning** or important information that should not be missed. Read all warnings and cautions carefully before starting the system for the first time.

NOTE Denotes important supplemental information.

Names of control keys, function keys, options and labels are shown in **bold** text. *Italicized* text is used for captions and to emphasize text.

In addition to reading this service manual, we encourage you to explore the SleepWorks and NwDb documentation, to take advantage of everything that XLTEK has designed the Hyppo headbox to do.

When going through the procedures, we recommend that you read the whole section first, before starting the sequence. Please follow the instructions carefully.

Warnings and Cautions

General Warnings

	Proper use of this device depends on careful reading of all instructions and labels that come with or on the system. Inaccurate Measures may be caused by incorrect application or use.
	The headbox is classified as an IP0 – ordinary degree of protection against ingress of water according to IEC 529.
	Inaccurate measurements may be caused by incorrect application or use.
	Only qualified personnel should operate this equipment.
	The computer used with the SleepWorks system must either be approved by Xltek and supplied as part of an IEC 601 approved system or it must be approved to IEC 950 or similar and kept outside of the patient environment.
	To ensure the validity of signals, do not operate the device near any sources of electromagnetic interference.
	Turn off the system power before cleaning. Prevent detergent solution or cold sterilization agents from seeping into the electronics of the system. Be careful around all connectors and edges. Do not use abrasive agents.
	Explosion Hazard: This system is not AP or APG rated. DO NOT USE this system in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.
	The accessories of this device may include several kinds of disposable, sterile needle electrodes. These needles are labeled as STERILE and the method of sterilization is documented on the packaging. These electrodes should not be used if the sterile packaging has been tampered with.
	The sale, distribution or use of this device is restricted to, by, or on order of a physician.

Electrical Warnings and Cautions

	The system is only intended for connection to a properly grounded electrical outlet.
	Periodically check the system integrity, the system leakage current, and the patient contact leakage current.
	Do NOT turn on the system power until all cables have been connected, verified and visually inspected for any damage. *Failure to inspect the cables may result in electrocution.*
	Do NOT connect or disconnect the patient headbox with the system power on.
	ELECTRICAL SHOCK HAZARD: Do NOT connect electrode inputs to earth ground. The patient headbox contains warning symbols reminding you that the connections are intended for isolated patient connections only. Connecting to an earth ground might result in electrocution. Do NOT connect to an electrical outlet controlled by a wall switch or dimmer.
	ELECTRICAL SHOCK HAZARD: Do NOT service the system. Refer servicing to qualified personnel only.

	The system uses a three-wire power cord with a hospital grade plug. The system is earth grounded. For grounding reliability, only connect the device to a hospital grade or hospital-only receptacle. Inspect the power cord often for fraying or other damage. Do NOT operate the system with a damaged power cord or plug.
	Do NOT place the isolation transformer on the floor.
	Plug only XLTEK-recommended components into the isolation transformer.

Masimo SET MS-7 Pulse Oximeter Warnings

	The Masimo SET MS-7 pulse oximeter is to be operated by qualified personnel only. This manual, accessory directions for use, all precautionary information, and specifications should be read before use.
	Explosion Hazard: Do not use the MS-7 pulse oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
	A pulse oximeter is intended for diagnostic purposes and should NOT be used as an apnea monitor.
	A pulse oximeter should be considered as an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.
	Leakage current must not exceed 100 microamperes. Measure when an external device is connected to the serial port.
	Significant levels of dysfunctional hemoglobins (HbCO or MetHb) may cause inaccurate measurements.
	Intravascular dyes such as indocyanine green or methylene blue may cause inaccurate measurements.
	Excessive illumination may cause inaccurate measurements or loss of pulse signal.
	Excessive patient movement may cause inaccurate measurements.
	Venous pulsations may cause inaccurate measurements.
	The MS board may be used during defibrillation, but the readings may be inaccurate for a short time.
	Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes that change usual arterial pigmentation, may cause erroneous readings.
	Loss of pulse signal can occur when the patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
	Loss of pulse signal can occur when there is arterial occlusion proximal to the sensor.
	Loss of pulse signal can occur when the patient is in cardiac arrest or is in shock.
	Tissue damage can occur due to incorrect placement of sensor.
	Do not immerse the sensor in water, solvents, or cleaning solutions. Do not sterilize the sensor by irradiation, steam, or ethylene oxide.

	Do not immerse the patient cable in water, solvents, or cleaning solutions (the patient cable connectors are not waterproof). Do not sterilize the patient cable by irradiation, steam, or ethylene oxide.

Masimo Pulse Oximeter Sensor Warnings

	Before use, carefully read the LNOP® sensor directions for use.
	Use only Masimo oximetry sensors for SpO_2 measurements. Other oxygen transducers (sensors) may cause improper MS-7 pulse oximeter performance.
	Tissue damage can be caused by incorrect application or use of an LNOP® sensor, for example, by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor directions for use to ensure skin integrity, and correct positioning and adhesion of the sensor.
	Do not use Masimo oximetry sensors during MRI scanning as it could potentially cause burns.
	Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter or intravascular line may cause inaccurate measurements.
	Loss of pulse signal can occur when the sensor is too tight.
	Do not use damaged LNOP® sensors. Do not use an LNOP® sensor with exposed optical components. Do no immerse the sensor in water, solvents, or cleaning solutions (the sensors and connectors are not waterproof). Do not sterilize by irradiation, steam, or ethylene oxide. See the cleaning instructions in the directions for use for reusable Masimo LNOP® sensors.
	Do not use damaged patient cables. Do no immerse the patient cables in water, solvents, or cleaning solutions (the patient cable connectors are not waterproof). Do not sterilize by irradiation, steam, or ethylene oxide. See the cleaning instructions in the directions for use for reusable Masimo patient cables.

Patient-Related Warnings and Cautions

	Disconnect the patient's recording electrodes from the system before your turn it on and off. Disconnecting the electrodes prevents shock.
	Connect all patient electrodes to fully electrically isolated physiological devices only. Connecting patient electrodes to any other device or external outlet may result in personal injury.
	The patient headbox accepts only touch-proof style electrode inputs. Do NOT attempt to use any other style of patient electrode input.
	Patient connections are NOT intended for direct cardiac contact.
	As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
	Do not place the monitor or external power supply in any position that might cause it to fall on the patient. Do not lift the monitor by the power supply cord or patient cable.

Unpacking

As you unpack your Hyppo, make sure that the following items are included:

- Hyppo headbox
- DC input box
- Breakout box
- Masimo oximeter probe
- Isolation box cable
- Isolation box
- Headbox cable
- Transducers

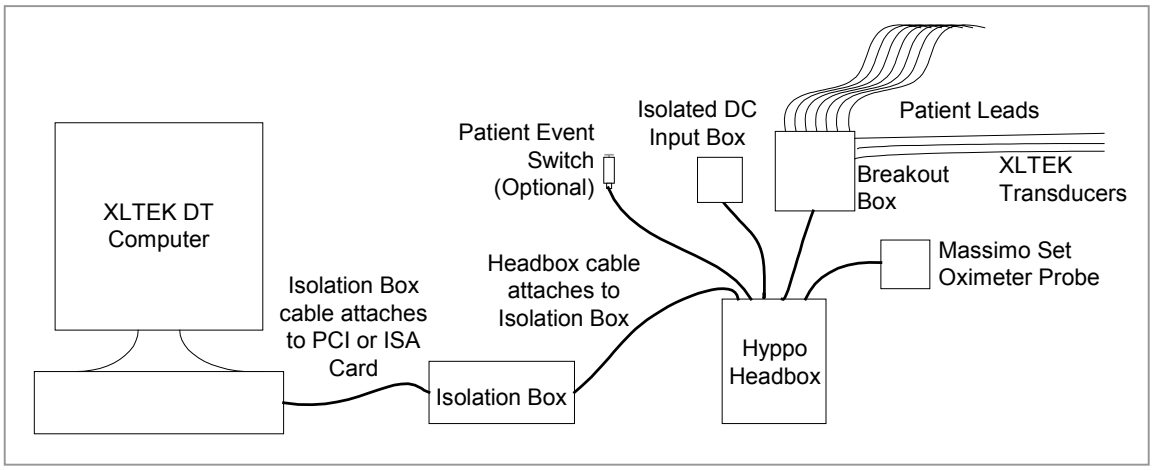
Optional Accessories:

- Patient event switch
- Electrodes
- Oximetry sensors

NOTE The Hyppo headbox should only be used with cables, transducers, electrodes, sensor and switches that are supplied or approved by XLTEK.

Setting Up

The Hyppo is designed to work with an XLTEK computer system along with NwDb and SleepWorks software.



Hardware Connections for a Hyppo Headbox

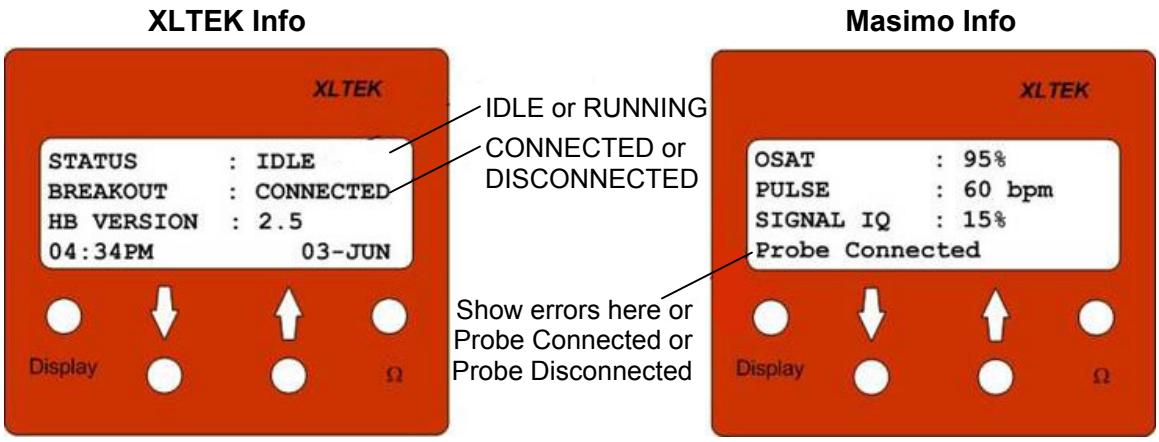
To Connect the Hyppo to the XLTEK Computer

1. Use the supplied Hyppo headbox cable to attach the Hyppo headbox to the Interface Box.
2. Attach the Interface Box to the PCI Card or the ISA card on the back of the XLTEK DT computer.
3. Attach the Isolated DC Input Box to the Hyppo Headbox.
4. If a Patient Event Switch is provided, insert the Patient Event Switch into the Patient Event connection on the headbox.
5. Plug the patient cable of the oximeter sensor into the MS-7 pulse oximeter port on the headbox.
6. Connect the breakout box to the headbox.
7. When you are ready to run a sleep study, insert the patient leads and transducers into the breakout box.

NOTE XLTEK designed the Hyppo for sleep (polysomnography) studies. For more information on running a sleep study refer to the SleepWorks documentation (choose **Help**->**SleepWorks Help**).

Operating Instructions

The LCD on the Hyppo presents different information depending on the current activity.



Using the Hyppo LCD Panel and Buttons

- When you first connect the Hyppo, the **XLTEK Info** screen is displayed.
- When you are acquiring data using a sensor with the Masimo Oximeter, press the **Display** button to display the **Masimo Info** screen.
- To return to the XLTEK Info screen, press the **Display** button.
- To initiate an impedance check, press the **Ω** button.
- When checking impedance, press the UP and DOWN arrow buttons to scroll through the channels.

Using the Hyppo with SleepWorks and NwDb Software

We custom-designed the Hyppo headbox to perform sleep studies on an XLTEK DT computer that is running XLTEK SleepWorks and NwDb software.

SleepWorks

SleepWorks records and processes the data acquired by the Hyppo headbox during a sleep study. Once the data is stored, SleepWorks provides tools that streamline the process of reviewing and analyzing sleep data.

During a sleep study, a variety of external transducers are used to measure parameters such as EEG, EOG, EMG, EKG (ECG), oxygen saturation (OSAT) body position, respiratory effort, airflow, snoring, etc. SleepWorks divides the data into epochs (typically 30 seconds long). During review, SleepWorks assigns a value indicating the dominant sleep stage during that epoch. SleepWorks can also detect significant events such as body movements, cessation of breathing, snoring, etc.

SleepWorks can automatically score a sleep study for you, or you can use the Sleep Stager tool to quickly navigate through a study to score and mark events. Once a study is scored, the Hypnogram and Sleep Summary views can help you to quickly uncover relationships between sleep stages and sleep events by plotting events and marking stages on interactive graphs. Then, you can use NwDb to produce reports and even compare the results of multiple reviewers.

NwDb

NwDb (NeuroWorks Database) is used to:

- Start a new sleep study
- Store sleep studies, along with notes and analysis, in a database.
- Monitor an ongoing sleep study from another station on the network
- Generate and customize reports

To Start a Routine Sleep Study

1. After preparing the patient and plugging the electrodes into the headbox, ensure that the headbox is properly attached to the computer.
2. Start NwDb.
3. Click the **New** toolbar button. Depending on your Sleep settings, the **Select Epoch Length** dialog box may appear. Select an epoch length and click **OK**. The **Study Information** window appears.
4. Enter the patient's information.
5. Click **OK**. The SleepWorks live recording screen appears.

To find out how to use SleepWorks to run a polysomnography study, refer to the **Sleep (Polysomnography)** section of **SleepWorks Help** (choose **Help**->**SleepWorks Help**).

Testing the Hyppo Headbox

The Hyppo headbox is fully assembled, tested and calibrated prior to being shipped to you. The following sections describe some test you can perform to verify the performance of the Hyppo headbox connections.

Calibration and Verification

There is no need to calibrate the NeuroWorks Software or the Hyppo headbox. All calibration is done at the factory before the system is shipped. To verify that the Hyppo headbox system is correctly calibrated, perform the following procedure:

1. Connect the Hyppo headbox to the acquisition station to an XLTEK Desktop computer and turn on the system.
2. Start NeuroWorks Database (NwDb).
3. To start a new study, click **New**.
4. Choose **Edit**->**Settings->Acquisition** tab.
5. In the Acquisition tab, set the **Reference Electrode** to **Common**.
6. Design four bipolar montages that take the difference of adjacent channels, for example, C3-CZ, C4-T4, T5-P3, etc.
7. Apply a sine wave of 5 millivolts ±2% peak-to-peak amplitude, 10 Hz to all channels of the group using a signal generator. Ensure that there is a 50 ohm load on the generator output if the generator is designed to deliver the specified level into this load.
8. Set the LFF filter to 0.1, the HFF filter to OFF and the Notch filter to OFF.
9. Verify that no sine wave is greater than 50 microvolts peak-to-peak. 50 microvolts represents gain match to 1%.

For more information on setting up a montage, see “Creating a Montage” in SleepWorks online help. To open the online help, choose **Help**->**SleepWorks Help**.

Channel Test

While in the SleepWorks live recording screen, a channel test may be performed to verify the integrity of the signal processing from the amplifier input through to the display. A channel test applies a test signal to all channels. This allows you to examine the waveforms on the screen to see if all of the channels are functioning.

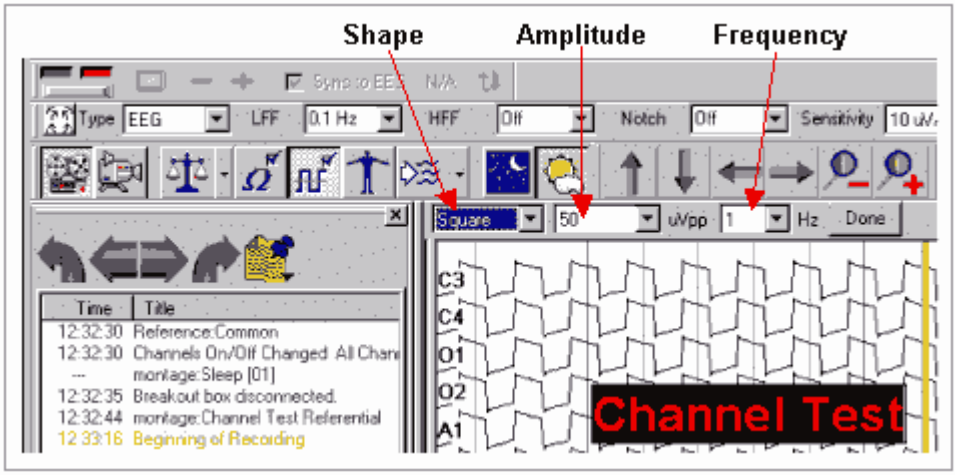
NOTE A channel test does not validate the connection from the patient electrode to the amplifier input.

To Run a Channel Test

1. To start the channel test, choose **Controls**->**Channel Test Signal**. The Channel Test control bar appears above the waveform window.
2. Using the channel test signal control, select the desired channel test shape, frequency and amplitude.
3. To stop the channel test and save the current settings, click **Done**.

Channel Test Signal Control

The Channel Test Signal control turns on the channel test signal according to the last settings saved and displays a **Test Signal** toolbar. The toolbar has controls for shape, amplitude and frequency.



Channel Test Signal Toolbar is located above the Trace Display

Impedance Check

An Impedance Check is performed to ensure that the electrode contact with the patient is satisfactory. You can perform an impedance check at any time during a study.

To Run an Impedance Check from the Hyppo LCD Panel

1. Press the Ω button. The headbox software calculates the impedance values and displays the results for the first eight channels on the LCD.
2. Press the DOWN arrow button to display the next group of channels. Press UP arrow button to move to the previous group of channels. If the impedance for a channel is less than 25 kOhms, then the actual impedance value is displayed on the LCD. If the value is greater than 25 kOhms, the value **OPEN** is displayed. If the value cannot be determined, **UNKN** (unknown) is displayed.
3. To end the Impedance Check, press the **Display** button.

To Run an Impedance Check from SleepWorks

When an impedance check is initiated, the software scans all channels (in auto scan mode).

To…	Do this…
Start the impedance check	Choose **Controls**->**Impedance Check**
Lock onto a channel	Click **Lock Channel** and then make adjustments to the electrode connection until satisfactory levels are achieved
Proceed to a full impedance check	Click **Release Lock**
End the impedance check	Click **End**
Save the impedance check as part of the study	Click **End and Start Recording**

An impedance check displays bar graphs that show the impedance of each electrode connection. A green bar indicates that the reading is below the set threshold. A red bar indicates the reading is above the threshold. To set the impedance threshold, click one of the **Threshold** buttons in the **Threshold Group** box on the right side of the **Check Impedance** box.

MS-7 Pulse Oximeter

The following topics list the specifications cleared by the FDA under K990966 for Masimo SET MS-7 board that is built into the Hyppo headbox. The MS-7 board connects to sensors and provides oxygen saturation, pulse rate, pulse waveform, and other output information via the SleepWorks system. The Hyppo headbox provides power and isolates the board from the main power and ground.

Masimo Patents

This device is covered under one or more of the following U.S. Patents: 5,482,036; 5,490,505; 5,632,272; 5,685,299; 5,758,644; 5,769,785; 6,002,952; 6,036,642; 6,067,462; 6,206,830; 6,157,850.

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Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts which would, alone, or in any combination with this device, fall within the scope of one or more of the patents relating to this device.

Indications for Use

The MS-7 pulse oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Masimo SET MS-7 pulse oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

How the Pulse Oximeter Works

The MS-7 pulse oximeter is based on three principles:

1. Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry).
2. The volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethsymography)
3. The arterio-venous shunting is highly variable, and that fluctuating absorbance by venous blood is a major component of noise during pulse. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by the blood is related to hemoglobin oxygen saturation.

The MS-7 pulse oximeter decomposes the red and infrared pulsatile absorbance signal into an arterial signal plus a noise component and calculates the ratio of the arterial signals without noise. The ratio of the two arterial pulse-added absorbance signals and its value is used to find the (SpO_2) saturation in an empirically derived equation into the MS-7 pulse oximeter's software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia states during motion and non-motion conditions.

The MS-7 pulse oximeter as well as traditional pulse oximetry determines SpO_2 by passing red and infrared light into a capillary bed and measuring changes in light

absorption during the pulsatile cycle. Red and infrared light-emitting diodes (LEDs) in oximetry sensors serve as the light sources, a photodiode serves as the photodetector.

Traditional pulse oximetry assumes that all pulsations in the light absorbance signal are caused by oscillations in the arterial blood volume. This assumes that the blood flow in the region of the sensor passes entirely through the capillary bed rather than through any arterio-venous shunts. The traditional pulse oximeter calculates the ratio of pulsatile absorbance (AC) to the mean absorbance (DC) at each of two wavelengths, 660 nm and 940 nm:

S(660) = AC(660)/DC(660)

S(940) = AC(940)/DC(940)

The oximeter then calculates the ratio of these two arterial pulse-added absorbance signals:

R = S(660)/S(940)

This value of R is used to find the saturation SpO_2 in a look-up table built into the oximeter's software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The MS-7 pulse oximeter assumes that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is the major component of noise during the pulse. MS-7 decomposes S(660) and S(940) into an arterial signal plus a noise component and calculates the ratio of the arterial signals without the noise:

S(660) = S1 + N1

S(940) = S2 + N2

R = S1/S2

Again, R is the ratio of two arterial pulse-added absorbance signals and its value is used to find the saturation SpO_2 in an empirically derived equation into the oximeter's software. The values in the empirically derived equation are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

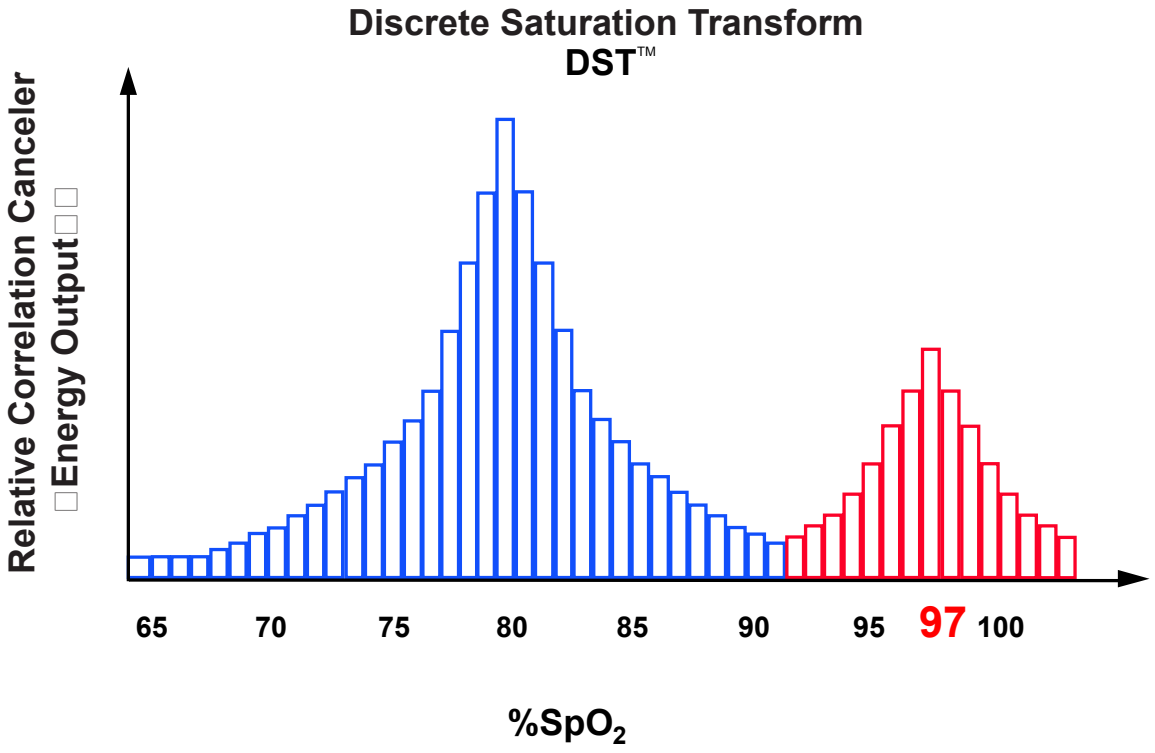
The above equations are combined and a noise reference (N') is determined:

N' = S(660) - S(940) x R

If there is no noise N' = 0: then S(660) = S(940) x R which is the same relationship for the traditional pulse oximeter.

The equation for the noise reference is based on the value of R, the value being sought to determine the SpO_2. The MS-7 software sweeps through possible values of R that correspond to SpO_2 values between 1% and 100% and generates an N' value for each

of these R values. The S(660) and S(940) signals are processed with each possible N' noise reference through an adaptive correlation canceller (ACC) which yields an output power for each possible value of R (i.e., each possible SpO_2 from 1% to 100%). The result is a Discrete Saturation Transform (DST™) plot of relative output power versus possible SpO_2 value as shown in the following figure where R corresponds to SpO_2 = 97%:



The DST plot has two peaks: the peak corresponding to the higher saturation is selected as the SpO_2 value. This entire sequence is repeated once every two seconds on the most recent four seconds of raw data. The MS-7 SpO_2 therefore corresponds to a running average of arterial hemoglobin saturation that is updated every two seconds.

MS-7 Pulse Oximeter Accessories

PC Series Cable: Connects the pulse oximeter module to the oximetry sensors. Transfers LED drive power to the oximetry sensors from the pulse oximeter. The pulse oximeter receives the detector signal from the oximetry sensor through the PC series cable.

LNOP® Series Oximetry Sensors: Measure the light absorption of blood from two light emitting diodes (LED's). Oxygen saturated blood absorbs light differently as compared to unsaturated blood. The amount of light absorbed by the blood is used to calculate the ratio of oxygenated hemoglobin to total hemoglobin in arterial blood. Available oximetry sensors:

Single Use Oximetry Sensor	For adults and pediatrics greater than 30 kg
	For pediatrics and small adults greater than 10 kg and less than 50 kg
	For neonates less than 10,000 gms
	For neonates less than 1,000 gms
Reusable Oximetry Sensor	For adults and pediatrics greater than 30 kg

Measurements

If the accuracy of any measurement does not seem reasonable, check the patient's vital signs by alternative means, and then check the MS-7 pulse oximeter for proper functioning.

Causes of Inaccurate Measurements

- Incorrect sensor application or use.
- Significant levels of dysfunctional hemoglobins (e.g., carboxyhemoglobin or methemoglobin).
- Intravascular dyes such as indocyanine green or methylene blue.
- Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight. Exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material.

Causes of Loss of Pulse Signal

- Sensor is too tight.
- Excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight.
- Blood pressure cuff is inflated on the same extremity as the one with a SpO^2 sensor attached.
- Patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
- Arterial occlusion is proximinal to the sensor.
- Patient is in cardiac arrest or is in shock.

Maintenance and Cleaning

To keep the Hyppo in good working condition, follow a regular schedule of preventive maintenance. Regular preventive maintenance does not involve access to the interior of the Hyppo headbox and components. For service problems that require corrective maintenance and/or internal component service, call XLTEK's Service department at 1-800-387-7516, or contact your local XLTEK representative.

Periodically check cable connections and electrodes for damage and wear. Inspect cables for bent pins. Replace frayed or worn cables. Also, regularly inspect and clean all system components, including:

- Connectors and jack ports
- Headbox and headbox cable
- Breakout box and cable
- DC box an cable
- Electrodes and accessories

The Hyppo is designed to be extremely portable in comparison previous, larger polysomnography systems. As such, the Hyppo is subject to increased daily wear and tear. Taking basic care of the system and avoiding extreme physical abuse helps prolong the lifespan of the Hyppo.

	Disconnect all cables from the Hyppo and the wall before wiping. Use a lint-free cloth. Do not use cleaners on any system component.
	Be careful not to allow any fluid to seep into the internal electronic components of the system.
	Do NOT leave the headbox attached to the computer when transporting the unit.
	Do NOT autoclave, pressure sterilize, or gas sterilize this headbox.
	Do NOT soak or immerse the headbox in any liquid.
	Use the cleaning solution sparingly. Excessive solution can flow into the headbox and cause damage to internal components.
	Do NOT touch, press, or rub the display panel with abrasive cleaning compounds, instruments, brushes, rough-surface materials, or bring them in contact with anything that could scratch the panel.
	Do NOT use petroleum-based or acetone solutions, or other harsh solvents, to clean the oximeter. These substances attack the device's materials and device failure can result.

Updating the Headbox Software

If this message appears—**This version of Wave requires headbox code version X.X or higher**—then you need to update the software that controls the headbox:

To update the headbox software:

1. The latest version of the headbox software is located on the NeuroWorks Installation CD in the NWorks\Ambulatory Update directory. Copy the headbox software files (AppLoader.bin, Download.amb, and FFS.bin) to the acquisition station's D:\NeuroWorks\Temp directory. If you cannot find these files, contact our customer service department to have them sent to you (1-800-387-7516 or support@xltek.com).
2. Attach the headbox that you wish to update to the recording machine.
3. Choose **Tools**->**Ambulatory Manager**.
4. To find out if any studies are stored in the headbox, click the **Storage Management** button.
5. Clear the memory. If necessary, upload the stored studies and then click **Clear Memory**. For more information see the topic "Upload an Ambulatory Study" in the Ambulatory Studies Tutorial.
6. To exit the Storage Management section, click **Done**.
7. Click **Headbox Administration**.
8. Click **Update Software**.
9. In the **File to Download** field, type D:\NeuroWorks\Temp\Download.amb and then click **Open**.
10. Click **Download**. Wait for the download to complete. (In version 2.4 and earlier, this creates two entries in the flash memory, which should be deleted later.)
11. The **Headbox Administration** box does not refresh to display the new version number until after it is closed and reopened.
    To close the Ambulatory Manager, click **Exit**.

Troubleshooting

If the acquired waveforms are flat, do not appear, or do not appear correctly (or as expected), shut down the computer for at least 10 seconds, and then set up the test again from the beginning. Shutting down and starting over resets the headbox and sometimes solves the problem. If you are still experiencing problems, here are some more solutions to try:

Troubleshooting Checklist

☐	Ask the patient to relax.
☐	Inspect your cables.
☐	Make sure that there is a tight connection between the Hyppo and the computer.
☐	Make sure that the patient electrodes are connected to the correct channel in the headbox.
☐	Make sure that the patient electrodes fit properly into the headbox (not loosely).
☐	Make sure that there are no apparent breaks in the patient electrode cables.
☐	If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternative means, and then check the MS-7 pulse oximeter for proper functioning.
☐	See "Causes of Inaccurate Measurements" and "Causes of Loss of Pulse Signal" in the "Measurements" section of this manual to find out what may be interfering with measurements taken by the MS-7 pulse oximeter.
☐	Are any of the electrodes touching? If so, they are causing a short circuit and will develop an artifact.
☐	Check the impedance.
☐	Unplug any other devices on the same circuit such as printers, mechanical beds, vacuum cleaners, or other potential sources of interference.
☐	Install a medical grade ground to make sure that your clinic has a properly grounded electrical system.
☐	Change the acquisition cable. You should always have a backup acquisition cable.
☐	Check the gain and timebase settings to ensure that they are appropriate for the current test. You may also want to check the LFF, HFF, and Notch Filter settings. Choose Edit->Settings->Montage. Right-click a cell in the appropriate column and select a value.

To Open the Troubleshooting Section of SleepWorks Online Help

1. Choose **Help**->**SleepWorks Help**.
2. Click the **Contents** tab.
3. Double-click the **Troubleshooting** book. The Troubleshooting book expands to show the contents.
4. Click a topic to display the content in the topic pane on the right.

Sensor Failure Messages

The LCD panel on the Hyppo displays the following sensor failure messages to inform you if there is a problem with the pulse oximeter sensor. Once the cause of the failure is cleared, the pulse oximeter will continue to operate.

Message	Comments
No Sensor Connected	
Open LEDs	Defective Sensor
Shorted LEDs	Defective Sensor
Low Perfusion	
Pulse Search	
Interference	Interference Detected
Sensor Off Patient	
Ambient Light	Too much ambient light
Unrecognized Sensor	
Low Signal IQ	
Masimo SET Active	

Error Codes

In the case that the Masimo Pulse Oximeter fails, the LCD panel of the Hyppo headbox may display one of these error messages followed by an error code. If a board failure occurs, all values are frozen and the pulse oximeter must be reset in order to continue operation. A board failure erases critical values such as Pulse Rate and SpO2. The headbox and pulse oximeter are reset automatically when you stop and restart the study.

Board Failure

Error Code	Meaning
1	MCU: ROM Checksum Failure
2	MCU: Internal RAM Test Failure
3	MCU: Timer Test Failure
4	MCU: Watchdog Failure
5	MCU: DSP Watchdog Failure
6	MCU: Invalid DSP ROM Flash Key
7	MCU: Invalid DSP command
8	MCU: DSP Never Request Boot Mode
9	MCU: Input or Output FIFO overflowed
32	DSP: Checksum Failure
33	DSP: Program Memory Test Failure
34	DSP: Data Memory Test Failure
35	DSP: Detector ACD Interrupt Test Failure
36	DSP: MCU Interrupt Failure
37	DSP: Diag Queue Overrun
38	DSP: Hardware Status Failure
39	DSP: Raw Queue Overrun
40	DSP: MCU Watch Dog Failure

Diagnostic Failure

The diagnostic failure codes are set to indicate which diagnostic(s) failed causing the Board Failure. There are generally two possible causes of these failures. First, the power provided to the MS-7 Board is out of specification. In this case, the failure may be cleared once the underlying cause is removed. In the second case, the MS-7 Board has an actual hardware failure and recovery is not possible.

Error Code	Meaning
0x0001	LED Ground
0x0002	Reference Voltage
0x0004	Digital Voltage
0x0008	DSP Voltage
0x0010	Positive LED Voltage
0x0020	Red Current Level
0x0040	IR Current Level
0x0080	Digital Ground
0x0100	Negative Preamp Voltage
0x0200	Preamp
0x0400	Positive Detector Voltage
0x0800	Negative Detector Voltage
0x1000	RFNC
0x2000	Sensor ID
0x4000	LED Current
0x8000	Analog Ground

Specifications

Hyppo Headbox Specifications

Number of channels	26 referential AC, 6 differential AC, 8 DC, integrated oxygen saturation and pulse rate.
Sampling Rate	200 Hz
A/D Conversion	22 bit synchronous sampling on AC channels 16 bit on DC channels
Input range	±10 mV on referential ±20 mV on differential ±10 V on DC
Resolution	0.03 μV sampling (0.3 μV storage) on AC channels 0.3 mV on DC channels
Input Impedance	> 50 MΩ
Input Noise	< 2 μV pk-pk @ full bandwidth
Common Mode Rejection Ratio	> 110 dB @ 60 Hz
Channel Crosstalk	< -60 dB

MS-7 Pulse Oximeter Specifications

RANGE	
Saturation (% SpO_2)	1% - 100%
Pulse Rate (bmp)	250 - 240
Perfusion	0.02% - 20%
ACCURACY	
Saturation (% SpO_2) – During No Motion Conditions[1]	
Adults, Pediatrics	70% - 100% ± 2 digits
	0% - 69% unspecified
Neonates	70% - 100% ± 3 digits
	0% - 69% unspecified
Saturation (% SpO_2) – During Motion Conditions[2,3]	
Adults, Pediatrics[2]	70% - 100% ± 3 digits
	0% - 69% unspecified
Neonates[3]	70% - 100% ± 3 digits
	0% - 69% unspecified
Pulse Rate (bmp) – During No Motion Conditions[1]	
Adults, Pediatrics, Neonates	250 to 240 ± 3 digits
Pulse Rate (bmp) – During No Motion Conditions[2,3]	
Adults, Pediatrics, Neonates	250 to 240 ± 5 digits
RESOLUTION	
Saturation (% SpO_2)	1%
Pulse Rate (bmp)	1
LOW PERFUSION PERFORMANCE[4]	
> 0.02% Pulse Amplitude	Saturation (% SpO_2) ± 2 digits
and % Transmission > 5%	Pulse Rate ± 3 digits

[1] The Masimo SET MS-7 pulse oximeter with LNOP•Adt sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[2] The Masimo SET MS-7 pulse oximeter with LNOP•Adt sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[3] The Masimo SET MS-7 pulse oximeter with LNOP-Neo and Neo Pt sensors has been validated for neonatal motion accuracy in human blood studies on neonates while moving the neonate's foot at 2 to 4 Hz at amplitude of 1 to 2 cm against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[4] The Masimo SET MS-7 pulse oximeter has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Getting Help

XLTEK is committed to providing you with support so you can operate the EMU128 Headbox with ease and confidence. If you need help, follow these steps to find a solution:

Step 1: Document the Incident

Carefully document the incident. If possible, note error messages, dialog box names and what you did before the problem occurred.

Step 2: Search the Online Documentation

Choose **Help**->**SleepWorks Help**.

Step 3: Restart the Computer

Often restarting the computer will solve a problem.

1. Close all applications.
2. Click the **Start** button on the Windows taskbar.
3. Choose **Shut Down…** from the Start menu.
4. Select **Restart the computer** and click **Yes**.

Step 4: Shut Down the Computer

Sometimes you need to shutdown the computer completely in order to solve a problem.

1. Click the **Start** button on the Windows taskbar.
2. Choose **Shut Down…** from the Start menu.
3. Select **Shut Down** and click **Yes**.
4. Turn the power off to the unit. Wait for 10 seconds. Turn the power back on.

Step 5: Contact Technical Support

First, write down the serial number (located on the back of the computer). Then phone XLTEK's 24-hour Customer Support at 1-800-387-7516 or contact XLTEK Customer Support at support@xltek.com.

We welcome your feedback and suggestions regarding any aspect of the SleepWorks system and software, the online help, our line of accessories, and our support services.

Warranty

Duration of Limited Warranty for XLTek Products

XLTek DT, and XLTek LT	1 year limited warranty
EEG Headbox	1 year limited warranty
Accessories	30 days limited warranty

Extent of Limited Warranty

XLTEK warrants to the end-user customer that XLTEK products will be free from defects in materials and workmanship for a specified time after the date of purchase by the customer. The duration of this limited warranty is as stated above. XLTEK does not warrant the operation of any product to be uninterrupted or error free. XLTEK does not extend this warranty to any third-party owners or users of the product. Warranties are voided on resold units.

XLTEK's limited warranty covers only those defects that arise as a result of normal use of the product, and do not apply if the product has been subjected to:

a. Improper or inadequate maintenance
b. Software or interfacing not supplied by XLTEK
c. Unauthorized modification or misuse
d. Improper site preparation or maintenance
e. Operation outside the product's environmental specifications

If XLTEK receives, during the applicable warranty period, notice of a defect in the product which is covered by this warranty, XLTEK shall either repair or replace the product, at its option, with a product that may be new or like-new, provided that it has functionality at least equal to that of the product being replaced.
All correspondence with XLTEK must specify both the model name and/or serial number, as it appears on the product.

Limitations of Warranty

XLTEK (nor any of its third-party suppliers) does not make any other warranties of any kind, whether expressed or implied with respect to XLTEK products. XLTEK and its third-party suppliers specifically disclaim the implied warranties of merchantability and fitness for a particular purpose.

To the extent that this Limited Warranty Statement is inconsistent with the law of the locality where the customer uses the XLTEK product, this Limited Warranty Statement shall be deemed modified to be consistent with such local law. Under such local law, certain limitations of this Limited Warranty Statement may not apply to the customer.

To the extent allowed by local law, the remedies provided in this Limited Warranty Statement are the customer's sole and exclusive remedies.
Except for the obligations specifically set forth in this warranty statement, in no event shall XLTEK be liable for any direct, indirect, special, incidental, or consequential damages, whether based on contract, tort, or any other legal theory and whether advised of the possibility of such damages.

XLTEK will make all reasonable efforts to satisfy the customer's needs in terms of providing a temporary replacement unit for an inadequately functioning XLTEK unit. XLTEK does not assume any responsibility for loss of income due to such an event.

Extended Warranty

As part of our program to continually support our valued customers with the most comprehensive service available, we are offering two different options to extend your standard warranty. In either case, it is your responsibility to contact: Head Office Customer Service department at 1-800-387-7516 in order to arrange the details of your extension.

Appendix 1: Schematics

Upon request, ***XLTEK*** will make available circuit diagrams, component part lists, descriptions, calibration instructions, and other information which will assist the user's appropriately qualified technical personnel to repair those parts of the Hyppo headbox which are designated by the manufacturer as repairable.

To receive the adjunct **Schematics** section of this service manual, contact an **XLTEK Customer Service Representative** at **1-800-387-7516** or **support@xltek.com**.